Reference 3

⑲日本国特許庁(JP)　⑪特許出願公表

⑫公表特許公報(A)　平5－502587

㊸公表　平成5年(1993)5月13日

㊿Int.Cl.⁵	識別記号	庁内整理番号		審査請求　未請求
C 12 P 21/08	ZNA	8214－4B		予備審査請求　未請求　部門(区分)　1(1)
A 61 K 39/395	ADU Z	8413－4C		
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㊹発明の名称　CDRグラフト抗－CEA抗体およびその製造方法

㉑特　願　平3－512027
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㊲翻訳文提出日　平4(1992)3月5日
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㉛指定国　AT，AT(広域特許)，AU，BB，BE(広域特許)，BF(広域特許)，BG，BJ(広域特許)，BR，CA，CF(広域特許)，CG(広域特許)，CH，CH(広域特許)，CI(広域特許)，CM(広域特許)，CS，DE，DE(広域特許)，DK，DK(広域特許)，ES，ES(広域特許)，FI，FR(広域特許)，GA(広域特許)，GB，GB(広域特許)，GN(広域特許)，GR(広域特許)，HU，IT(広域特許)，JP，KP，KR，LK，LU，LU(広域特許)，MC，MG，ML(広域特許)，MN，MR(広域特許)，MW，NL，NL(広域特許)，NO，PL，RO，SD，SE，SE(広域特許)，SN(広域特許)，SU，TD(広域特許)，TG(広域特許)，US

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請求の範囲

1．人化抗体分子（HAM）において、癌胎児性抗原に対して特異性を有し、可変ドメインの相補性決定領域（CDR）の少なくとも一つはマウスモノクローナル抗体A5B7（A5B7MAb）に由来し、HAMの残りの免疫グロブリン部分はヒト免疫グロブリンに由来する抗原結合部位を有する人化抗体。

2．キメラ人化抗体である「請求項1」記載のHAM。

3．CDRグラフト人化抗体である「請求項1」記載のHAM。

4．組換えDNA技術によって製造される「請求項1～3」のいずれかに記載のHAM。

5．完全な抗体分子、またはFab、Fab'、$(Fab')_2$もしくはFVフラグメント、または単一鎖抗体フラグメントから構成される「請求項1～4」のいずれかに記載のHAM。

6．それにエフェクターまたはレポーター分子が結合した「請求項1～5」のいずれかに記載のHAM。

7．重鎖および／または軽鎖は、LAY、POM、TUR、TEI、KOL、NEWM、REIまたはEU可変領域フレームワーク配列から構成される「請求項3～6」のいずれかに記載のCDRグラフトHAM。

8．重鎖および軽鎖両者において、LAY可変領域フレームワーク配列から構成される「請求項7」記載のCDRグラフトHAM。

9．軽鎖可変領域の位置24～34（CDR1）、50～56（CDR2）および92～96または89～97（CDR3）にA5B7CDRを有する「請求項3～8」のいずれかに記載のCDRグラフトHAM。

10．軽鎖可変領域の位置1、2および／または3、46、47、49、60、70、84、85および87の1つまたは2以上好ましくは少なくとも位置46および47にA5B7残基を有する「請求項3～9」のいずれかに記載のCDRグラフトHAM。

11．重鎖可変領域の位置24～35または26～35（CDR1）、50～65（CDR2）および95～100または94～100（CDR3）において、A5B7CDRを有する「請求項3～10」のいずれかに記載のCDRグラフトHAM。

12．重鎖可変領域の位置23および／または24、71および／または73、48および／または49、69、76および／または78、80、88および／または91ならびに6の1つまたは2以上にA5B7残基を有する「請求項3～11」のいずれかに記載のCDRグラフトHAM。

13．軽鎖の位置1、2、3、4、46および71、同時にとくに位置21、47および73、重鎖の位置1、24、48、49、72、73、76および93、同時にとくに位置82bおよび66においてA5B7残基からなる「請求項8」記載のCDRグラフトHAM。

14．軽鎖の位置24～34（CDR1）、50～56（CDR2）および89～97（CDR3）、ならびに重鎖の位置26～35（CDR1）、50～65（CDR2）および95～102（CDR3）において、A5B7CDRを有する「請求項8」記載のCDRグラフトHAM。

15．「請求項1～14」のいずれかに記載のHAMを医薬的に許容される担形剤、希釈剤または担体と配合してなる治療または診断用組成物。

16．「請求項15」記載の治療または診断用組成物の有効量をヒト対象に投与することからなる治療または診断方法。

17．「請求項1～14」のいずれかに記載のHAMの製造方法において、

(a) 可変ドメインCDRの少なくとも1個がA5B7MAbから誘導され、抗体鎖の残りの免疫グロブリン由来部分はヒト免疫グロブリンから誘導される可変

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⑧1指定国　AT,AT(広域特許),AU,BB,BE(広域特許),BF(広域特許),BG,BJ(広域特許),BR,CA,CF(広域特許),CG(広域特許),CH,CH(広域特許),CI(広域特許),CM(広域特許),CS,DE,DE(広域特許),DK,DK(広域特許),ES,ES(広域特許),FI,FR(広域特許),GA(広域特許),GB,GB(広域特許),GN(広域特許),GR(広域特許),HU,IT(広域特許),JP,KP,KR,LK,LU,LU(広域特許),MC,MG,ML(広域特許),MN,MR(広域特許),MW,NL,NL(広域特許),NO,PL,RO,SD,SE,SE(広域特許),SN(広域特許),SU,TD(広域特許),TG(広域特許),US

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(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

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(54) Title: CDR GRAFTED ANTI-CEA ANTIBODIES AND THEIR PRODUCTION

(57) Abstract

The present invention provides humanised antibody molecules (HAMs) having specificity for carcinoembryonic antigen (CEA) and having an antigen binding site wherein at least one of the complementarity determining regions (CDRs) of the variable domains is derived from the mouse monoclonal antibody A5B7 (A5B7 MAb) and the remaining immunoglobulin-derived parts of the HAM are derived fron a human immunoglobulin. The HAMs may be chimeric humanised antibodies or CDR-grafted humanised antibodies and are preferably produced by recombinant DNA techniques. The HAMs are useful for *in vivo* diagnosis and therapy.

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(54) Title: CDR GRAFTED ANTI-CEA ANTIBODIES AND THEIR PRODUCTION

(57) Abstract

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+ See back of page

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